volume of the resultant preparation, remove an accurately measured representative portion from each container. Dilute the solution thus obtained with sufficient distilled water to obtain a solution containing 1 milligram of cefmenoxime per milliliter (estimated). Transfer 4.0 milliliters of this solution to a 50-milliliter volumetric flask, add 20 milliliters of internal standard solution and dilute to volume with mobile phase to obtain a solution containing 80 micrograms of cefmenoxime per milliliter (estimated).

(iii) *System suitability requirements*—(A) *Tailing factor.* The tailing factor (*T*) for the cefmenoxime peak is satisfactory if it is not more than 1.6 at 5 percent of peak height.

(B) *Efficiency of the column.* The efficiency of the column (*n*) is satisfactory if it is greater than 1,200 theoretical plates for the cefmenoxime peak.

(C) *Resolution.* The resolution (*R*) between the peak for cefmenoxime and phthalimide is satisfactory if it is not less than 2.3.

(D) *Coefficient of variation.* The coefficient of variation (S_R in percent) of 5 replicate injections is satisfactory if it is not more than 2.0 percent. If the system suitability requirements have been met, then proceed as described in §436.363(b) of this chapter.

(iv) *Calculations*—(A) *Micrograms per milligram.* Calculate the micrograms of cefmenoxime per milligram as follows:

$$\text{Micrograms of cefmenoxime per milligram} = \frac{\text{T3}R_u \times P_3 \times 100 \times d}{R_s \times C_u (100 - \text{L} - \text{S})}$$

where:

R_u=Area of the cefmenoxime peak in the chromatogram of the sample/Area of internal standard peak;

R_s=Area of the cefmenoxime peak in the chromatogram of the cefmenoxime working standard/Area of internal standard peak;≤

P_s=Cefmenoxime activity in the cefmenoxime working standard solution in micrograms per milliliter;

C_u=Milligrams of sample per milliliter of sample solution;

d=Dilution factor of the sample;

L=Percent loss on drying (determined as directed in paragraph (b)(4) of this section); and

S=Percent sodium carbonate (determined as directed in paragraph (b)(6) of this section).

(B) *Milligrams of cefmenoxime per vial.* Calculate the cefmenoxime content of the vial as follows:

$$\text{Milligrams of cefmenoxime per vial} = \frac{R_u \times P_s \times d}{R_s \times 1{,}000}$$

where:

R_u=Area of the cefmenoxime peak in the chromatogram of the sample/Area of internal standard peak;

R_s=Area of the cefmenoxime peak in the chromatogram of the cefmenoxime working standard/Area of internal standard peak;

P_s=Cefmenoxime activity in the cefmenoxime working standard solution in micrograms per milliliter; and

d=Dilution factor of the sample.

(2) *Sterility.* Proceed as directed in §436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in §436.32(b) of this chapter, using a solution containing 60 milligrams of cefmenoxime per milliliter.

(4) *Loss on drying.* Proceed as directed in §436.200(a) of this chapter.

(5) *pH.* Proceed as directed in §436.202 of this chapter, using an aqueous solution containing 100 milligrams per milliliter.

(6) *Sodium carbonate content.* Proceed as directed in §436.364 of this chapter.

[53 FR 13403, Apr. 25, 1988; 53 FR 19369, May 27, 1988]

§442.223 Sterile cephaloridine.

The requirements for certification and the tests and methods of assay for sterile cephaloridine packaged for dispensing are described in §442.23a.

[39 FR 19040, May 30, 1974, as amended at 55 FR 11583, Mar. 29, 1990]

§442.225 Cephalothin sodium injectable dosage forms.

§442.225a Sterile sodium cephalothin.

The requirements for certification and the tests and methods of assay for sterile sodium cephalothin packaged for dispensing are described in §442.25a.

[39 FR 19040, May 30, 1974. Redesignated at 40 FR 11351, Mar. 11, 1975]